

PAIN & POLICY STUDIES GROUP



WHO Collaborating Center
for Policy and Communications
in Cancer Care

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May 25, 1999

Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

Re: Docket No. 98N-1265

Dear Sir or Madam:

I read the proposed MOU with great interest and deep concern about the theory of public health and regulation expressed therein.

If there are public health problems that involve compounding by particular pharmacies or pharmacists it is essential to correct such problems at their source.

I do not understand how you proposed to limit interstate commerce would address directly a public health problem caused by individuals. In what way would errant practices of certain pharmacies or pharmacists be corrected by limiting the amount of compounded drugs leaving a state?

If there was a problem of prescription drug diversion, would FDA propose limiting the amount of drug that could be manufactured and distributed throughout the United States in the hope that the behavior of certain errant pharmacists would somehow be changed?

The public deserves to be protected from substandard practices and it is government's responsibility to do so. Is clamping a ceiling on interstate commerce a reasonable way to curtail practices that fall outside of accepted standards? Or would it be better to ensure that complaints against such entities are lodged and investigated?

There is no shortage of regulatory authority at the state level of government that is directly responsible for licensing and disciplining pharmacies and pharmacists. May I suggest that you reconsider your approach and instead a) work with individual states to ensure that concerns and complaints about compounding are addressed directly, and b) encourage development of cooperative agreements between the states to coordinate the processing of such complaints where necessary.

There is also an obligation of government not to interfere with legitimate professional practice and improve public health. Indeed, why should government restrain the efforts of a class

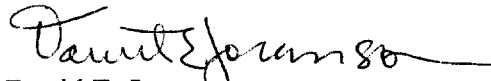
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of professional pharmacists who are in good faith producing a) tailored products which may enhance the therapeutic benefit of pharmaceuticals as well as, b) professional services which could enhance patients' knowledge and understanding of their treatment, and thus compliance.

I hope that you will take these comments under advisement.

Sincere regards,

A handwritten signature in black ink, appearing to read "David E. Joranson", with a long, sweeping horizontal line extending to the right.

David E. Joranson
Senior Scientist, Director

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